8-2-04

1651

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Fiona M. Wood et al.

Serial No. 10/068,299

Filed: 6 February 2002

For: CELL SUSPENSION PREPARATION TECHNIQUE AND DEVICE

) Atty. Docket 37264.10.0
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) Art Unit: 1651
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) Examiner: Jean C. Witz
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To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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By Theresa Russek
Theresa Russek

PRELIMINARY AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

SIR:

The present Preliminary Amendment is filed concurrent with the Response to the Restriction Requirement mailed 30 June 2004, the unextended period for response which is set to expire 30 July 2004. Prior to examination, please amend the above-identified application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks/Arguments begin on page 9 of this paper.

08/04/2004 AWONDAF1 00000077 061910 10068299
01 FC:2201 129.00 OP
02 FC:2202 55.00 DA 17.00 OP

08/04/2004 LSOUKS 00000092 061910 10068299
01 FC:2201 43.00 DA

FORM PTO-1083
Docket No. 37264.10.0
In re application of Wood, et al.

Serial No. 10/068,299

Filed: February 6, 2002

For: Cell Suspension Preparation Technique and Device

COMMISSIONER FOR PATENTS
Alexandria, VA 22313-1450

Sir: Transmitted herewith is an amendment in the above-identified application.

[x] Applicant(s) is/are entitled to small entity status in accordance with 37 CFR 1.27.
[ ] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
[ ] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.
[ ] No additional fee is required. The fee has been calculated as shown below:

	(Col. 1) CLAIMS REMAINING AFTER AMENDMENT		(Col. 2) HIGHEST NO. PREVIOUSLY PAID FOR	(Col. 3) PRESENT EXTRA
TOTAL	28	MINUS	** 20	= 8
INDEP.	8	MINUS	*** ~~5~~ 4	= ~~3~~ 4
☐ FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				

	SMALL ENTITY RATE	SMALL ENTITY ADDIT. FEE		OTHER THAN A SMALL ENTITY RATE	OTHER THAN A SMALL ENTITY ADDIT. FEE
	$9	$ 17.00 → 72.00	OR	$18	$0
	$43	$129.00 → 172.00 − 129 = 43.00		$86	$0
		$0			$0
TOTAL ADDIT. FEE		$146.00	OR	TOTAL	$0

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment or the number of claims originally filed.

[ ] Please charge by Deposit Account No. 061910 in the amount of $_____. A duplicate copy of this sheet is attached.
[x] A check in the amount of $146.00 is attached.
[x] The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 061910. A duplicate copy of this sheet is attached.

[x] Any filing fees under 37 CFR 1.16 for the presentation of extra claims.

[x] Any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,

Kara K. Smith

Kara K. Smith, 49,079

In the Claims

Please amend the claims as follows:

1. (Original) A method for preparing a cell suspension suitable for application to a patient, which method comprises the steps of:

(a) subjecting a tissue sample including cells suitable for grafting to a patient, to at least a physical and or chemical dissociating means capable of dissociating cellular stratum in the tissue sample;

(b) removing the tissue sample from the dissociating means used in step (a) and harvesting in the presence of a nutrient solution cells from the tissue sample, cells suitable for grafting on to a patient wherein the nutrient solution is (i) free of xenogenic serum, (ii) capable of maintaining the viability of the cells until applied to a patient and (iii) is suitable for direct application to a region on a patient undergoing tissue grafting; and

(c) filtering the cellular suspension produced according to step (b) to remove large cellular conglomerates.

2. (Original) A method according to claim 1 wherein the enzyme suitable for dissociating cohesive pieces of tissue stratum in the sample is trypsin or a trypsin-like enzyme.

3. (Original) A method according to claim 2 wherein the enzyme is selected from the group consisting of trypsin, trypsin-EDTA, dispase, collagenase, thermolysin, pronase, hyaluronidase, pancreatin, elastase and papain.

4. (Original) A method according to claim 1 wherein the nutrient solution is Hartmann's solution.

5. (Currently Amended) A cell suspension produced according to ~~the method of claim 1~~ a method comprising the steps of:

(a) subjecting a tissue sample including cells suitable for grafting to a patient, to at least a physical and or chemical dissociating means capable of dissociating cellular stratum in the tissue sample;

(b) removing the tissue sample from the dissociating means used in step (a) and harvesting in the presence of a nutrient solution cells from the tissue sample, cells suitable for grafting on to a patient wherein the nutrient solution is (i) free of xenogenic serum, (ii) capable of maintaining the viability of the cells until applied to a patient and (iii) is suitable for direct application to a region on a patient undergoing tissue grafting; and

(c) filtering the cellular suspension produced according to step (b) to remove large cellular conglomerates.

6. (Original) A cell suspension according to claim 5 prepared from autologous cells.

7. (Original) A method of treating a patient in need of graft surgery, said method comprising the steps of:

(a) preparing a cell suspension according to the method of claim; and

(b) administering the suspension directly to a region on the patient that requires a cell graft in a manner that facilitates spreading of the cell suspension in a relatively even distribution over the graft region.

8. (Original) Use of a cellular suspension suitable for grafts, which suspension is prepared according to the following steps:

(a) subjecting a tissue sample including cells suitable for grafting to a patient, to an enzyme suitable for dissociating cohesive pieces of the tissue stratum in the sample;

(b) removing the sample from the enzyme solution used in step (a) and harvesting in the presence of a nutrient solution cells from the tissue sample, which cells are suitable for grafting on to a patient wherein the nutrient solution is (i) free of xenogenic serum, (ii) capable of maintaining the viability of the cells until applied to a patient and (iii) is suitable for direct application to a region on a patient undergoing tissue grafting; and

(c) filtering the cellular suspension produced according to step (b) to remove large cellular conglomerates;

for the preparation of therapeutic preparation suitable for the treatment of tissue disorders requiring grafting.

9. (Original) The use according to claim 8 wherein the nutrient solution is Hartmann's solution.

10. (Original) An apparatus for developing a tissue regeneration solution, said apparatus comprising:

(a) a heating means suitable for heating an enzyme solution to a required temperature and which is capable of maintaining that solution at the desired temperature for a suitable amount of time; and

(b) a filter recess comprising a filter means capable of separating large cellular congregates from a cellular suspension.

11. (Original) The apparatus according to claim 10, which additionally comprises a reservoir capable of holding a tissue sample and a nutrient solution.

12. (Original) The apparatus according to claim 10, which includes one or more fluid containment wells for storage of fluids.

13. (Original) An apparatus for developing a tissue regeneration solution, comprising a first and second member wherein:

(i) the first member includes:

(a) a heating means suitable for heating an enzyme solution to a required temperature and which is capable of maintaining that solution at the desired temperature for a suitable amount of time;

(b) a filter recess comprising a filter means capable of separating large cellular congregates from a cellular suspension;

(c) at least a fluid containment well for storage of nutrient solution;

(ii) the second member forms a reservoir capable of withholding a tissue sample and nutrient solution in fluid containment; and

wherein the first member provides a seat upon which the second member may be placed during manipulation of the tissue.

14. (New) A cell suspension according to claim 5 wherein the physical and or chemical dissociating means comprises a chemical dissociating means comprising an enzyme solution.

15. (New) A cell suspension according to claim 14 wherein the enzyme solution comprises an enzyme selected from the group consisting of trypsin, trypsin-EDTA, dispase, collagenase, thermolysin, pronase, hyaluronidase, pancreatin, elastase and papain.

16. (New) A cell suspension according to claim 15 wherein the enzyme solution comprises between about 5% and about 0.1% trypsin per volume of solution.

17. (New) A cell suspension according to claim 16 wherein the enzyme solution comprises between about 2.5% and about 0.25% trypsin per volume of solution.

18. (New) A cell suspension according to claim 14 wherein the enzyme solution is heated.

19. (New) A cell suspension according to claim 18 wherein the enzyme solution is heated to a temperature between about 30 degrees Celsius and about 37 degrees Celsius.

20. (New) A cell suspension according to claim 14 wherein the enzyme solution is calcium and magnesium free.

21. (New) A cell suspension according to claim 20 wherein the enzyme solution is provided in a calcium and magnesium ion free phosphate buffered saline.

22. (New) A cell suspension according to claim 5 wherein the tissue sample comprises a tissue biopsy derived from skin.

23. (New) A cell suspension according to claim 5 wherein the nutrient solution comprises a salt solution.

24. (New) A cell suspension according to claim 5 wherein the nutrient solution comprises physiological saline.

25. (New) A cell suspension according to claim 5 wherein the filtering step comprises the use of a filter size between about 50μm and about 200μm.

26. (New) A cell suspension according to claim 25 wherein the filtering step comprises the use of a filter size between about 75μm and about 150μm.

27. (New) A cell suspension produced according to a method comprising the steps of:

(a) subjecting a tissue sample including cells suitable for grafting to a patient, to a heated enzyme solution capable of dissociating cellular stratum in the tissue sample, the heated enzyme solution being calcium and magnesium free and comprising an enzyme selected from the group consisting of trypsin, trypsin-EDTA, dispase, collagenase, thermolysin, pronase, hyaluronidase, pancreatin, elastase and papain;

(b) removing the tissue sample from the dissociating means used in step (a) and harvesting in the presence of a nutrient solution cells from the tissue sample, cells suitable for grafting on to a patient wherein the nutrient solution comprises physiological saline and is (i) free of xenogenic serum, (ii) capable of maintaining the viability of the cells until applied to a patient and (iii) is suitable for direct application to a region on a patient undergoing tissue grafting; and

(c) filtering the cellular suspension produced according to step (b) with a filter size between about 50μm and about 200μm to remove large cellular conglomerates.

28. (New) A cell suspension produced according a method comprising the steps of:

(a) subjecting a tissue sample including cells suitable for grafting to a patient, to a heated enzyme solution capable of dissociating cellular stratum in the tissue sample, the heated enzyme solution comprising a calcium and magnesium ion free phosphate buffered saline and between about between about 5% and about 0.1% trypsin per volume of solution, the heated enzyme solution being heated to a temperature between about 30 degrees Celsius and about 37 degrees Celsius;

(b) removing the tissue sample from the dissociating means used in step (a) and harvesting in the presence of a nutrient solution cells from the tissue sample, cells suitable for grafting on to a patient wherein the nutrient solution comprises physiological saline and is (i) free of xenogenic serum, (ii) capable of maintaining the viability of the cells until applied to a patient and (iii) is suitable for direct application to a region on a patient undergoing tissue grafting; and

(c) filtering the cellular suspension produced according to step (b) with a filter size between about 75μm and about 150μm to remove large cellular conglomerates.